UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Subcategory Docket: 06-CV-11337-PBS
THIS DOCUMENT RELATES TO	)	Judge Patti B. Saris
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al., No. 06-CV-11337-PBS	)	Magistrate Judge Marianne B. Bowler

ABBOTT LABORATORIES INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION *IN LIMINE* TO EXCLUDE CERTAIN OPINIONS PROFFERED BY PLAINTIFFS' EXPERT MARK G. DUGGAN, PH.D

Dated: June 26, 2009

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES
(continued)

Page

STATUTES & RULES

MISCELLANEOUS

INTRODUCTION

This Court has correctly emphasized that damages will not be presumed in this or any other False Claims Act case. Instead, Plaintiffs must prove that Abbott's alleged fraud has caused the federal Medicare program and each state Medicaid program to incur damages with respect to the four Subject Drugs (Vancomycin, saline, dextrose, and sterile water). The proper way to do this would be to review each claim that the Plaintiffs allege to be false, or at a minimum to use a statistically-sound sampling methodology capable of reliably demonstrating (i) that the universe of allegedly false claims were all paid by reference to an Abbott-reported price (for, if they were not, then the damages cannot be attributed to Abbott); and (ii) the actual damages amount – i.e., the amount that the programs overpaid. Plaintiffs in this case do neither.

After 14 years of investigation and litigation, Plaintiffs load all of their damages hopes on the shoulders of Dr. Mark G. Duggan, an economics professor who has never before been certified by a court as an expert in any subject. Dr. Duggan ultimately pegs the Government's alleged overpayment at $107.1 million. As discussed below, however, only about half of this calculated damages figure (or "difference," as Duggan prefers to call it) is based on actual claims data. The remainder is made from whole cloth.

Duggan never had the opportunity to review all of the allegedly false claims at issue. Indeed, this task could never be accomplished because Plaintiffs did not preserve all such claims, allowing a vast number of them to be destroyed. But even where Plaintiffs did have actual claims data, Duggan often chose not to use it. On the Medicaid side, he only reviewed claims data (itself incomplete) from 10 high-expenditure states.[1] Duggan reviewed this data, made certain conclusions, and then extrapolated out both to backfill gaps in the data for the 10 states

[1] The chart attached as Ex. A depicts the claims data Duggan did, and did not, review for Medicaid.

and to manufacture a "difference" figure for the 39 states where he reviewed *no data at all*. On the Medicare side, Duggan reviewed patchy data from a few, cherry-picked Medicare Carriers, and "extrapolated" away from there.[2] In total, fully $57,094,409 of Plaintiffs' claimed damages are attributable to Duggan's "extrapolation" over states and Carriers where he had no actual evidence.

Far from a scientific exercise, Duggan's "extrapolation" is not an extension of reliable, known facts, but is instead an exaggeration of self-selected and biased information. *First*, not even Duggan can argue that the sample claim data he reviewed is random – a fact that, by itself, undermines the validity of his work. *Second*, Duggan does nothing to establish that the subset of claims he reviewed are representative of claims for all of the missing Carriers and states (because they are not). It is undisputed that different Medicare Carriers and different state Medicaid programs used widely divergent methods to set their payment levels for drugs. Some payors based their payment levels on benchmarks other than the compendia – such as a MAC, U&C, or some specially-devised fee schedule for home infusion products – that may have had nothing at all to do with any Abbott-reported price (and, thus, these claims cannot be assigned as damages against Abbott).

Duggan's "extrapolation" cannot account for this known variability, so he simply ignored it and calculated a "difference" every time a state paid more than the amount he thinks they should have paid, which he calls a "but for" price. But ignoring these facts does not make them go away, it merely leads to absurd results. As discussed in Part I.A.1 below, Duggan's failure to account for different payment methodologies leads to several scenarios where he concludes that states should have paid providers *nothing* for these products, forcing the providers to take a

[2] The chart attached as Ex. B illustrates the minimal data Duggan reviewed for Medicare.

significant loss on every product dispensed to a Medicaid patient. This is clearly not what the states ever intended, and yet this absurd conclusion forms the basis of Duggan's "difference" calculation and Plaintiffs' damages claim.

Duggan's approach is inconsistent with this Court's prior holdings, and many of the assumptions baked into his "extrapolation" methodology are demonstrably false. Neither the facts, nor logic, nor any peer-reviewed literature support the sort of machinations Duggan undertook to produce a $100+ million damages figure. Tellingly, Duggan does not even attempt to assign a confidence interval to his calculations.

This Court should not allow Plaintiffs to proceed to trial, and to inflame and confuse the jury, with sky-high damages numbers that are grounded not in science, but in sleight-of-hand. Accordingly, Abbott requests an order ruling inadmissible, pursuant to *Daubert* and its progeny, Duggan's proffered testimony to the extent it relies on his flawed extrapolation methodology. Abbott files this motion now because exclusion of the challenged aspects of Duggan's opinions provides another reason to grant certain aspects of Abbott's Motion for Partial Summary Judgment, filed contemporaneously. Other than Duggan, Plaintiffs have no evidence to prove causation and damages as to the extrapolated claims, requiring summary judgment in Abbott's favor.[3]

DUGGAN'S "DIFFERENCE" MODEL

To prove "actual damages," Plaintiffs rely exclusively upon Duggan, a Professor of Economics at the University of Maryland. The AWP cases mark Duggan's first foray into the "damages expert" world; indeed, prior to the Texas AWP litigation (also involving Ven-A-Care),

[3] *See, e.g., Albert v. Warner-Lambert Co.*, 234 F. Supp. 2d 101, 106-07 (D. Mass. 2002) (excluding expert testimony on damages and granting defendant's motion for summary judgment); *see also, e.g., Dunn v. Sandoz Pharm. Corp.*, 275 F. Supp. 2d 672, 684 (M.D.N.C. 2003).

Duggan had not been retained to compute damages in any litigation. (SOF ¶ 81.)[4] He has never testified as an expert before a jury on any subject. (*Id.*)

In his report, Duggan claims to have calculated a $107.1 million difference:

> between (1) what the federal government reimbursed for certain pharmaceutical products [the Subject Drugs] provided to Medicaid and Medicare recipients during the eleven-year period 1991 and 2001 and (2) what the federal government would have reimbursed for the same products during the same time period if prices reflective of the actual prices at which Abbott was transacting business had been used for the AWP, WAC, and Direct Price of Abbott products.

(*Id.* ¶ 82.)[5] Of this figure, $64.7 million relates to Medicaid and $42.4 million to Medicare. (*Id.*) Interestingly, while Plaintiffs offer Duggan to establish their FCA damages, Duggan himself has refused to describe what he calculated as damages, only "differences."[6] (SOF ¶ 83.) And rightly so. His opinion reflects an abstract mathematical subtraction and not an approximation of alleged damages.

A. What Duggan Did For Medicaid.

While Duggan calculated a "difference" for each Medicaid claim, his methodology depended upon what state the claim came from and what data he chose to review.

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[4] Citations to the Local Rule 56.1 Statement of Undisputed Material Facts Supporting Abbott Laboratories Inc.'s Motion for Partial Summary Judgment and Abbott Laboratories, Inc.'s Motion in Limine to Exclude Certain Opinions Proffered by Plaintiff's Expert Mark G. Duggan, Ph.D, filed contemporaneously, are referenced as (SOF ¶ ___).

[5] The number was originally $108.2 million, but it dropped after Plaintiffs abandoned their claims relating to Ohio Medicaid.

[6] The following exchange is typical: "Q. For the time periods and products that you do consider in your calculation, are you yourself providing an opinion on the amount at which the federal government has been damaged by Abbott's alleged misconduct in this case? Mr. Lavine: Object to form. A. So once again, in the report I try to be very transparent about what exactly I'm doing. And one thing that I make clear is that – that I try very hard to make clear is that I'm not advocating the reporting of a specific product for a specific time period and so forth. But my analysis does what it states that it sets out to do, which is to calculate the difference plugging in the prices that I do for AWPs and so forth. And so it is – given all of the supporting narrative and analyses in my report, the $108.2 million difference represents what it says in the very first sentence. So it doesn't fit – the problem is that I have this analysis which doesn't fit neatly into the question." (*Id.* ¶ 83.)

1. States And Periods With Some Data.

For 10 states, Duggan reviewed a patchwork of claims data covering some part of the alleged damages period: 1991-2001.[7] To make his difference calculation for these claims, Duggan first determined the "but for" price that he felt the states should have paid absent Abbott's alleged fraud, by assigning what he considered to be "correct" AWPs, WACs, and DPs for each of the 44 NDCs at issue and for each quarter.[8] Duggan then determined whether the state actually paid more on a given claim than his asserted "but for" price. If it did, then the overage was added to his "difference" figure.

This approach does not determine the formulas actually used, or the actual basis of payment, for any claim. Duggan admittedly did not concern himself with that critical issue. (*Id.* ¶ 121.) He simply calculated the difference between what was paid and what he opines should have been paid. Accordingly, despite this Court's clear orders to the contrary, this approach calculates a "difference" even when the claim was not, in fact, *paid* based on any compendia-reported price (AWP, WAC, or DP). For example, this approach yields a "difference" (which Plaintiffs then claim as "damages") even for claims paid based on a state MAC. (*Id.* ¶ 124.) Duggan made no effort to determine which states used MACs for the relevant NDCs or for what time periods; which claims were paid based on state MACs; or what impact any compendia-reported Abbott price had on the establishment of those MACs. (*Id.* ¶ 122-23.) Similarly, Duggan's approach yields a "difference" even when a claim was paid based on physicians' U&C

[7] The 10 states are Illinois, Florida, California, New Jersey, New York, Kentucky, Missouri, Michigan, Louisiana, and Wisconsin. Not coincidentally, these states have relatively high spending on the Subject Drugs. (*See* Ex. A; SOF ¶ 88.)

[8] To arrive at his "but for" prices, Duggan focused on the average transaction price for sales of the Subject Drugs to pharmacies (as opposed to hospitals, which were the primary purchasers of these products). With respect to AWP, Duggan added a 25% markup to the average pharmacy transaction price for the Subject Drugs, ostensibly to account for the normal compendia scaling factor. (*Id.* ¶ 84.) Abbott has numerous concerns about Duggan's purported "but for" prices, and certainly does not agree that they are accurate, but those issues are beyond the scope of this motion. Abbott reserves its right to challenge any aspect of Duggan's opinions in the future.

charges or based on a special payment schedule applicable to infusion products – which, again, have no tie to any reported price for an Abbott drug.

2. States And Periods With No Data At All.

When Duggan either did not have, or chose not to review, data relating to each alleged false claim to perform his "difference" calculation – which is most of the time – he "extrapolated." He did so both within the 10 states where he had some data (to fill gaps for time periods where no data was available), and also across 39 states where he reviewed no data at all.

Extrapolation Within States. Even for the 10 states where Duggan reviewed some claims data, there are significant gaps. (*See* Ex. A; SOF ¶ 128.) For example, Michigan produced claims data only for five of the 44 quarters at issue (1991-2001), while the Illinois claims data covers all but the first quarter. (*Id.*) Duggan nonetheless calculated a "difference" for nearly every quarter for each NDC, even those for which he reviewed no claims data.

To cover the missing quarters, Duggan calculated what he calls a "difference ratio" for the nearest quarter where he had actual claims data. (SOF ¶ 129.) The "difference ratio" is Duggan's total "difference" for an NDC divided by the state's total expenditures for that NDC in a given quarter. For example, if Duggan's "difference" was $100 and the state's total expenditure for that NDC and quarter was $200, then the "difference ratio" would be 50%. Duggan then multiplied the "difference ratio" by the total expenditures for the missing quarters (aggregate figures that he obtained from CMS), and assigned the resulting figure as the dollar "difference" that the state overpaid during those time periods. (*Id.*) Other than a minor scaling adjustment, Duggan's analysis assumes (without basis) that the difference between what was paid and what Duggan thinks should have been paid would remain constant during periods for which there is no claims data.

Extrapolation Across States. Finally, Duggan reviewed no claims data at all for the

vast majority of states (39 of them).[9] (That is not to say that more claims data does not exist. The Government gave Duggan some additional data, including substantially complete data for Texas, but he chose not to use it. (*Id.* ¶¶ 97-107).) So, Duggan calculated damages for those states by resorting to another unreliable form of "extrapolation."

Duggan had to start with a sample for his extrapolation, so he used the 10 states discussed above (which, not coincidentally, are large, high-dollar usage states).[10] Duggan did nothing to establish that these states constitute a representative sample, or to discuss what made them appropriate for this exercise, but he used them anyway as the foundation for his extrapolation.

To compute a "difference" for these 39 states where he reviewed no evidence, Duggan first used his 10-state sample to derive a composite "difference ratio," which is the percentage amount that he believes the 10 states overpaid for Abbott's Subject Drugs.[11] (*Id.* ¶ 131-132.) Duggan then multiplied that composite "difference ratio" by the total dollar expenditures for the Subject Drugs in each of the 39 no-data states to arrive at a dollar value "difference" totaling more than $27 million. (*Id.* ¶ 133-35.)

Once again, this academic calculation is entirely divorced from the facts. Duggan ignores the methodology actually used by the states to pay any particular claim, and he assumes without verification that all of the payments in the 39 no-data states were set on the same bases as those in the 10 "sample" states. Duggan does not account for key differences that render that assumption demonstrably false. He does not account for the prevalence of MACs on the Subject

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[9] The 39 states include all remaining states but Ohio and Arizona, plus D.C.

[10] Indiana does not fit entirely within either category because Duggan calculated a "difference" for this state by extrapolating from the state of Illinois. (*Id.* ¶ 87.) Because Duggan did not use detailed claims data in computing his "difference" for Indiana, we include it in the extrapolated states category.

[11] Only quarters where the 10 states produced data are included in calculating the composite difference ratio. (*Id.* ¶ 132.) Because of large gaps in the data, particularly early in the damage period, Duggan's "difference ratio" for some quarters is based on only a small subset of the 10 states, making his broader extrapolation even less reliable. (*Id.* ¶ 128.)

Drugs in these various states, nor the levels of those MACs. If a state had a MAC in place (like Texas and Alabama, for instance), then the payments per claim tend to be dramatically lower than those in states that based their payments on compendia prices, making it even more difficult to extrapolate reliable "differences" for those states using data derived from others. Nor does Duggan's analysis account for the many state Medicaid programs that knowingly paid a margin on drug ingredient costs to provide a profit to providers, subsidize inadequate dispensing fees, and ensure continued access to care. (*Id.* ¶¶ 23-27, 30-32, 38, 125-126, 160, 163.) This was especially true for the infusion drugs at issue here, the dispensing of which bears no resemblance to the retail pharmacy reimbursement model used by most states. (*Id.* ¶¶ 21-27, 30, 38, 160.)[12] But Duggan does not mention these facts, or attempt to account for them in his theoretical model in any way.

In total, Duggan's Medicaid extrapolation accounts for over half of the $64,669,351 in Medicaid damages claimed by Plaintiffs – $4,876,976 for in-state extrapolation, and $27,806,024 for extrapolation across states, for a total of $32,683,002.

B. What Duggan Did For Medicare.

Unlike Medicaid, Medicare, of course, pays based not on NDCs (which identify manufacturers), but on HCPCS codes (also called "J-Codes"), which group all similar products without identifying the manufacturer. A single J-Code often includes many different products from many different manufacturers, all of which may have different prices. Despite these

[12] Ironically, much of this evidence comes from the same accounting firm, Myers & Stauffer, upon which Duggan relies in his report. (*See, e.g.*, 2002 M&S report for California: "In every dispensing cost survey performed by Myers & Stauffer in which data on the provision of intravenous services was collected, the provision of this service has been associated with higher dispensing costs. . . . This [$42] margin [on ingredient cost reimbursement] typically allows for adequate reimbursement of the pharmacy's dispensing cost. So long as the ingredient reimbursement rate remains at AWP minus 9% or any other relatively "high" level, the need for the Department to set a separate dispensing fee for intravenous drugs is somewhat mitigated by the margins realized on ingredient reimbursement.") (*Id.* ¶ 25.).)

differences, each Carrier establishes a single payment amount for the J-Code, regardless which product is actually used by the provider. In general, the Carriers do this by determining the median of all AWPs for all products, and from all manufacturers, within the J-Code and then using that median AWP as the basis for payment. (*Id.* ¶¶ 143-144.) The Carriers were essentially free to construct their own arrays. (*Id.* ¶ 145.) Some utilized many AWPs within the J-Code, and some used only a small subset – often resulting in dramatic differences in median AWPs (and thus in payment levels) among the Carriers. (*Id.* ¶¶ 150-151.) This is because a median-based payment level, unlike a mathematical average, is literally just the middle of a distribution. One assembles an array of prices and the price in the middle becomes the payment level. The number of prices used in the array can thus significantly affect the result, and there was no uniform practice among the Carriers as to how many prices to include in their arrays. (*Id.* ¶¶ 145, 150-151.) Moreover, there were many situations in which the Carriers did not use the median AWP as a payment benchmark at all, but instead utilized a different metric, such as the providers' U&C or the lowest branded AWP. (*Id.* ¶ 149.) All of these factors render it impossible to make reliable assumptions about payment behavior across Carriers. Just as he did with respect to Medicaid, however, Duggan assumed away these facts and calculated a Medicare "difference" anyway.

1. Carriers And Periods With Some Data.

The 44 NDCs at issue in this case span 5 J-Codes, for which Duggan calculated "differences."[13] The DOJ provided Duggan with a patchwork of pricing arrays from certain

[13] The five J-Codes are J3370 (500 mg Vancomycin HCL), J7030 (1000 ml normal saline), J7040 (500 ml normal saline), J7050 (250 ml normal saline solution), and J7060 (500 ml 5 percent Dextrose/Water). (*Id.* ¶ 142.)

Carriers.[14] (Ex. B; SOF ¶¶ 117-118.) To calculate a "difference" for the rare situations when he had an actual array, Duggan first identified any Abbott AWPs included in the array and replaced them with his revised, "but-for" AWPs. (SOF ¶ 147.) He then recalculated the median AWP, creating a new allowable amount for that J-Code-quarter/year. (*Id.* ¶ 148.)

Duggan next determined whether his new allowable amount was lower than what the Carrier actually paid for a given claim. If it was, he assessed that "difference" as damages against Abbott, regardless whether the particular claim was paid for an Abbott product or some other product in the same J-Code. (*Id.* ¶ 149.) Finally, Duggan made no effort to limit his ascribed "difference" to Abbott's market share, despite this Court's instruction in the Track 1 trial that a defendant can only be assessed damages consistent with its market share. (*Id.* ¶ 142.)

Based on this exercise, Duggan calculated a "difference ratio" for each Carrier by dividing the total dollar "difference" by the total amount paid by the Carrier.

2. Carriers And Periods With No Data At All.

The DOJ's production of pricing arrays from Part B Carriers is particularly sporadic and incomplete. (*Id.* ¶¶ 116, 143.) Where he had no actual evidence, Duggan again "extrapolated."

Extrapolation Within Carriers. Even for those Carriers where Duggan had at least some pricing arrays, there were often missing quarters and even years for which no arrays were available. There is no way to tell for certain whether an Abbott AWP was included as part of the missing arrays (and thus may have factored into the payment amounts). The absence of proof did not dissuade Duggan from assigning a "difference." He simply multiplied the "difference ratio" discussed above for a given Carrier by the entire amount paid by the Carrier during the

[14] As this Court knows, Medicare employed contractors to both determine payment allowables and to pay claims. In this case, most claims for J3370 (Vancomycin HCL) were processed by four Durable Medical Equipment Regional Carriers ("DMERCs"); claims for the other J-Codes were processed by over 90 different Part B "Carrier" codes. (*Id.* ¶ 143.)

missing time periods to arrive at a dollar "difference" figure, which Plaintiffs now claim as damages against Abbott. (*Id.* ¶¶ 152-153.) Once again, this "difference" takes no account of whether Abbott's reported price was a factor in the payment at all, whether a particular claim was paid for an Abbott product versus some other product in the J-Code, or whether the Carrier in fact based its payments on some benchmark other than the median AWP. The dollar impact of Duggan's guesswork is significant. For example, the DOJ provided Duggan with arrays for one Carrier, Florida Blue Shield, but the data was so incomplete that nearly 70% of the "difference" that Duggan calculates for this Carrier is extrapolated. (*Id.* ¶ 153.) In total, even where Duggan was able to review at least some Carrier data (the Plaintiffs' best case scenario), the data was so patchy that fully $8,702,961 of Duggan's calculated "difference" for these Carriers is the result of extrapolation. (*Id.*)

Extrapolation Across Carriers. The machinations Duggan went through to calculate his "difference" for all of the Medicare Carriers where he reviewed no data whatsoever are even more extraordinary. Duggan first looked to the Medicare aggregate payment data from CMS and determined the allowable amount that was paid by Carriers during the missing time periods. If that amount happened to be close enough to an AWP for an Abbott product often enough to meet some subjective standard that Duggan devised in his own mind, then he deemed it appropriate, with no ability to verify things empirically, to backfill these missing time periods with his "difference" findings from other Carriers. (*Id.* ¶ 154.)[15]

Duggan then calculated, based on his work with the few Carrier arrays he had, a combined "difference ratio" for each J-Code, representing the average percentage that he believes the Carriers "overpaid" by paying at a level above his chosen "but for" allowable

[15] Duggan apparently regarded any price within about 10% of an Abbott AWP to be close enough for inclusion. Duggan's standard for what was "often enough" appears to be entirely subjective.

amounts. (*Id.*) Finally, Duggan computed his dollar value "difference" for all Carriers with no arrays by multiplying, for each J-Code for each quarter, each Carrier's total expenditures for the J-Code by his difference ratio for that J-Code and that quarter, and summing those results, with a minor scaling adjustment. (*Id.*)

This speculative extrapolation across Carriers where there is no proof of actual arrays accounts for $15,708,446 of the Medicare "difference" that Plaintiffs now seek from Abbott. (*Id.*) Together with the "within Carrier" extrapolation discussed above, Plaintiffs rely upon Duggan's extrapolation for more than half of their alleged Medicare damages ($24,411,407 of $42,391,387).

ARGUMENT

I. THE COURT SHOULD EXCLUDE DUGGAN'S EXTRAPOLATED "DIFFERENCE" CALCULATIONS.

A. Applicable Standards For Expert Testimony.

An expert's testimony is not admissible where it is not "based upon sufficient facts or data," or does not result from applying reliable principles and methods to the facts of the case. Fed. R. Evid. 702. Methodology "is the 'central focus of a *Daubert* inquiry,' but the court 'may evaluate the data offered to support an expert's bottom-line opinions to determine if the data provides adequate support to mark the expert's testimony as reliable." *United States ex rel. Loughren v. UnumProvident Corp.*, 604 F. Supp. 2d 259, 264 (D. Mass. 2009) (Saris, J.) (quoting *Ruiz-Troche v. PepsiCola of P.R. Bottling Co.*, 161 F.3d 77, 81 (1st Cir. 1998)). The factors used to evaluate the admissibility of expert testimony include (1) whether the theory or technique can be and has been tested; (2) whether the technique has been subject to peer review and publication; (3) the technique's known or potential rate of error; (4) the existence of standards controlling the technique's operation; and (5) the level of the theory's or technique's

acceptance within the relevant discipline. *See Loughren*, 604 F. Supp. 2d at 264.

Plaintiffs have the burden of establishing the admissibility of Duggan's testimony. *See id.* "The Court's vigilant exercise of this gate-keeper role is critical because of the latitude given to expert witnesses to express their opinions on matters about which they have no firsthand knowledge, and because an expert's testimony may be given greater weight by the jury due to the expert's background and approach." *Id.* at 265 (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 595 (1993) and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 148 (1999)).

These concerns are heightened in the FCA context, where damages are trebled. In such cases, courts should carefully scrutinize the reliability of damage computations.[16] After all, "[u]nder the False Claims Act," no less than any other context, "damages must be proven with reasonable certainty." *United States ex rel. Ervin & Assocs., Inc. v. Hamilton Sec. Group, Inc.*, 370 F. Supp. 2d 18, 55 (D.D.C. 2005). And actual damages are "not within the realm of reasonable certainty" when they are "remote, speculative, [or] hypothetical." *Albert v. Warner-Lambert Co.*, 234 F. Supp. 2d 101, 103 (D. Mass. 2003); *see also United States v. Collyer Insulated Wire Co.*, 94 F. Supp. 493, 499 (D.R.I. 1950) (damages in FCA cases cannot be the subject of "speculation and guesswork").

The methodologies that Duggan used to compute his extrapolated "differences" for many of the allegedly false Medicaid and Medicare claims at issue here are neither consistent with accepted standards nor reliable. They should not be allowed to serve as the basis for a damages award, let alone treble damages, and should be excluded.

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[16] *See* Breckinridge L. Wilcox & Jefferson M. Gray, *Extrapolation of Damages and Penalties in Fraud Cases: A Slippery Slope in FCA Actions*, Business Crimes Bulletin (Dec. 2000) ("[T]he FCA's provisions for multiple damages and penalties mean that the financial impact of any claims erroneously treated as improper under the extrapolation will be greatly magnified."); *accord Euromodas v. Zanella*, 368 F.3d 11, 17 (1st Cir. 2004) ("Antitrust liability is strong medicine (for example, it exposes a defendant to treble damages, see 15 U.S.C. § 15), and thus section 1 of the Sherman Act has been authoritatively interpreted to limit the inferences that may be drawn from ambiguous evidence.").

In situations, like this one, where FCA plaintiffs have attempted to prove damages by resorting to extrapolation methods not grounded in reliable scientific methodology, courts have not hesitated to say "no." *Loughren*, 604 F. Supp. 2d at 264-69 (rejecting extrapolation to determine number of false claims because expert did not support his sampling approach, and approach was susceptible to manipulation and significant error); *Collyer*, 94 F. Supp. at 498-99 (rejecting Government's attempt in FCA case to extrapolate damages because sample of defective wire was not drawn from all relevant sources); *United States ex rel. Whipple v. Rockwell Space Operations Co.*, No. Civ. A.H-96-3626, 2002 WL 864246, at *12 (S.D. Tex. Apr. 3, 2002) (rejecting extrapolation of damages in FCA case from one set of employees to other work groups that were not analyzed, as extrapolation was "impermissible speculation") (citing *Collyer*); *Cf. Albert*, 234 F. Supp. 2d at 106 n.7 (rejecting expert's extrapolation of findings in lost profits case, reasoning "there is no basis whatsoever for an extrapolation from the nursing home market to the hospital market"). That is what should happen here.

B. Medicaid.

1. Across State Extrapolation.

Duggan's extrapolation of "differences" from 10 states (with incomplete data), to 39 others (with no data at all), suffers from the same flaws this Court identified in *Loughren*, including a lack of support for the extrapolation approach used and a demonstrated susceptibility to manipulation and absurd results.

The Sample. The first and most glaring problem is that Duggan failed to begin with an appropriate sample. Instead of using a random sample of representative claims paid by all of the states under consideration, Duggan simply plucked 10 states with high expenditures on the

NDCs at issue out of the range of information provided to him by the DOJ.[17] Duggan himself admits that the "10 are not a random sample of the initial 48," and that he instead "focused attention on the largest states." (*Id.* ¶ 89.)

In stark contrast to common sampling and extrapolation standards, Duggan's report contains *no discussion at all* of how he chose the "sample" he uses in his extrapolation. *Compare Loughren*, 604 F. Supp. 2d at 261 ("According to his expert report, Mercurio considered and rejected using simple random sampling, the most basic sampling procedure (the one familiar even to lawyers and judges), and stratified sampling . . . ."). Indeed, unlike in *Loughren* – where the expert at least purported to follow *some* methodology ("cohort sampling"), and yet was still excluded – there is no evidence that Duggan employed *any* "sampling" methodology at all. Instead, he just took 10 high-expenditure states and ran with them. Not surprisingly, Abbott has been unable to locate any precedent in law or literature for Duggan's approach, which may have been results-oriented or perhaps merely a "sample of convenience." *Id.* at 266 (noting that expert "failed to cite any peer-reviewed literature to support his novel approach"). Perhaps because he did not employ a standard or logical sampling method, Duggan does not even attempt to assign a margin of error, or confidence interval, to his extrapolated "difference" analysis so that the Court can evaluate the reliability of his work. Duggan thus fails to give the Court even the broad deviation estimates that the expert provided in *Loughren. Id.* at 269 (a key factor in excluding expert's analysis was the "extremely wide confidence interval").

It is not as though Duggan had nowhere to turn for guidance as to sample selection. To the contrary, CMS itself has developed detailed protocols for Medicare Carriers that use

[17] Due to the wide variation in how states and Medicare contractors paid for the drugs at issue, Abbott has consistently maintained that a representative sample of claims in this case would include information for each state/Carrier, each NDC/J-Code, and for each time period (quarter/year). (*See* Dkt. No. 5173 at 7.)

"statistical sampling in their reviews to calculate and project [i.e., extrapolate] overpayment amounts to be recovered by recoupment, offset or otherwise." CMS Manual System, Pub. 100-08, Medicare Program Integrity, Transmittal 114, *Change in Statistical Sampling Instructions* ("Transmittal 114") at 3.10.1.1; *see also* Program Memorandum (Carriers), Transmittal B-03-022, *Use of Statistical Sampling for Overpayment Estimation When Performing Administrative Reviews of Part B Claims*. (SOF ¶ 90.) CMS's protocols would have required Duggan, among other things, to ensure that each allegedly false claim at issue (the population he is studying) had a "known probability of selection," or that his "universe and sampling frame . . . [included] all relevant claims for the period under review." (*Id.*) That is clearly not true here; only claims from 10 states (and even then, only for certain time periods) had any chance of being included in Duggan's "sample." He did not use any of the sampling techniques – simple random sampling, systematic sampling, stratified sampling, or cluster sampling – recognized by CMS. (*See id.*) And contrary to the CMS protocols, Duggan did not, presumably because he could not, "provide complete documentation of the sampling methodology that [he] followed." (*Id.*).

Nor is Duggan's approach consistent with the *Reference Manual on Scientific Evidence*, commonly used by courts to evaluate statistical extrapolations. *See, e.g.*, *Loughren*, 604 F. Supp. 2d at 269. Duggan did not draw his sample from "the population [of] the whole class of units that are of interest" – here the universe of allegedly false claims from all states and contractors – such that any given claim had a "known, nonzero probability of being chosen." *See* David H. Kaye & David A. Freedman, *Reference Guide to Statistics*, in *Reference Manual on Scientific Evidence* at 90, 100 (Fed. Judicial Ctr. 2d ed. 2000). Nor did he include a standard error or confidence interval. *Id.* at 117 ("Whenever possible, an estimate should be accompanied by its standard error").

Not only is Duggan's 10-state sample not random, it is upwardly biased and obviously susceptible to manipulation. A telling example is Duggan's failure to include Texas in his 10-state sample. Duggan received detailed claims data covering 1994 through 2006 from Texas for use in this case; indeed, Duggan had utilized additional data from Texas already in his previous expert work relating to the separate case that Texas brought against Abbott (which involved many of the NDCs at issue here). (*Id.* ¶¶ 95, 97.) Because Texas is indisputably a large drug expenditure state (it ranked third in total drug spending in 1996), one would expect Duggan to include Texas in his 10-state sample. (*Id.* ¶ 96.) He did not. Duggan claimed that he excluded Texas because that state's spending for the Subject Drugs ranked just 20th among the 50 states. (*Id.* ¶ 98.) But Duggan also knew full well that Texas' spending on the Subject Drugs was relatively low *because Texas implemented MACs* on many of these products.[18] So, he excluded from his 10-state sample a state that he knew would have exhibited less of a "difference," leading to a reduction of both the dollar value "difference" for the sample states and the "difference ratio" percentage that Duggan used for his extrapolation to the 39 no-data states. Worse yet, having refused to analyze the *actual* claims data for Texas that was available to him (and that he had already analyzed in his prior work in the Texas case), Duggan nevertheless used the "difference ratio" calculated from his upwardly biased 10-state sample to compute a dollar value "difference" *for Texas* (which Plaintiffs now claim as damages).[19] Given the clear potential for manipulation and abuse inherent in his methodology (not to mention the actual

[18] (*Id.*¶ 99. (Duggan's report: "For example, some states used SMAC prices for one or more Complaint products at some time during the period of interest. This frequently occurred in the Texas Medicaid program for Abbott products . . . .").)

[19] Additional examples of potential manipulation in Plaintiffs' hand-picked sample abound. For example, Abbott subpoenaed detailed claims data from Maryland covering the time period 1991 to 2001 and produced that data to the DOJ. (*Id.* ¶¶ 104-07.) Maryland set MACs on the Subject Drugs for much of the damage period. Although Duggan received the Maryland claims data from the DOJ, he chose not to include this state in his 10-state sample. (*Id.*) (*See also id.* ¶¶ 100-03 (regarding claims data received, but not used, from Pennsylvania); ¶¶ 108 (regarding elimination of Ohio from his analysis).)

manipulation and abuse evidenced by Duggan's biased data selection), this Court cannot allow Plaintiffs to present Duggan's conclusions to the jury. *See Loughren*, 604 F. Supp. 2d at 269 (excluding expert where the opponent "presented convincing evidence that the [expert's] technique is susceptible to manipulation and significant error"); *see also Albert*, 234 F. Supp. 2d at 106 n.7; *United States v. Skoknek*, 933 F. Supp. 1108, 1115-18 (D. Mass. 1996) (rejecting Government's extrapolation loss calculation used in sentencing of psychiatrist-defendant in criminal Medicare billing fraud case because the "extrapolation was not done according to the usual statistical formalities," but instead was a "convenience sample garnered by a unit whose purpose is to investigate fraud"); *Allgood v. Gen. Motors Corp.*, No. 102CV1077, 2006 WL 2669337, at *9-11 (S.D. Ind. Sept. 18, 2006) (rejecting expert testimony when expert "failed to offer any scientific justification for his sample selection choices, which are central to the reliability of his methodology," and there was evidence of "selection bias"); *Collyer*, 94 F.Supp. at 498-99; *Whipple*, 2002 WL 864246 at *12.[20]

Extension Of The Sample. That Duggan's sample ignores statistical standards is only the beginning of the problem. The deficiencies are magnified by the way he applies that sample, from 10 high-usage states, to calculate "differences" for 39 other states. The result is a number that is not remotely representative of the larger population being measured.[21]

[20] *See also Mensasha Corp. v. News Am. Mktg. In-Store Inc.*, 238 F. Supp. 2d 1024, 1030 (N.D. Ill. 2003) (journalist survey excluded in part because he failed to gather responses from a representative sample accurately representing the target population); *United States v. Mikos*, No. 02 CR 137, 2003 WL 22922197, at *4 (N.D. Ill. Dec. 9, 2003) (finding FBI database of bullet samples could not be the basis of expert testimony because there was no evidence "that the samples were gathered in any approved scientific manner so as to be considered as representative of the bullet population as a whole").

[21] Two experts retained by Abbott, Dr. James W. Hughes (a Professor of Economics at Bates College) and Mr. Steven J. Young (an accountant with considerable healthcare consulting experience), have provided extensive testimony in their reports and depositions detailing the shortcomings of Duggan's extrapolated "differences." Those criticisms can by found on pages 41-46 (Medicaid) and 18-20 (Medicare) of Dr. Hughes's report and pages 14-21, 25-26 (Medicaid), and 21-22 (Medicare) of Mr. Young's report. (*See* Ex. C, Declaration of James W. Hughes and attached expert report); Ex. D, Declaration of Steven J. Young and attached expert report.)

For one thing, Duggan's extrapolation presumes that the impact of his revised "but for" prices on Medicaid spending would be the same for claims paid by the 39 no-data states as it was for the 10 states in his non-random sample. This idea, in turn, depends on the unstated assumption that the 39 extrapolated states focused on the same factors to establish ingredient payment levels as did the 10 states with data. As shown above, however, that assumption is false. For example, implementation of a MAC for a drug dramatically changes both *how* a state reimbursed a particular NDC and the *amount* paid. (*Id.* ¶¶ 105, 108, 136.) Yet Duggan admits that he made no effort to determine which states established MACs for the Subject Drugs, or to compare the relative prevalence of state MACs among the 10 and 39 state groups, respectively. (*Id.* ¶¶ 122-123.)

Duggan ignored these critical details and instead simply reviewed the basic adjudication formulas (*e.g.*, whether states used AWP, WAC, or DP) to establish comparability between the states. (*Id.* ¶ 110.) Even the Government recognizes that this approach is unacceptable, however, as shown in a 2004 report from OIG. (*Id.* ¶ 136.) Using 2001 data, OIG found that states' unit payment amounts for the same drugs varied considerably: "On average the highest paying State paid 477 percent more per drug than the lowest paying State for each of the 28 drugs in our sample." (*Id.*) Not surprisingly, OIG found *much greater variation in reimbursements for generic drugs*, with the median and average variations of 374% and 1230%, respectively, between the highest and lowest paying states. (*Id.*) Even the "average difference between the State at the 25th percentile and the State the 75th percentile (*i.e.*, the interquartile range) was 63 percent for the 10 non-innovator multisource drugs." (*Id.*) In short, OIG found that various states' payment amounts for the same generic drugs were all over the proverbial map.

OIG believed this variability was due to differences in state MAC pricing, as well as differences in states' definitions of "usual and customary charge" and the frequency with which drugs were reimbursed at U&C. (*Id.*). Specifically, the OIG stated: "*Even States with the same formula* for estimating pharmacy acquisition demonstrated variation in their average annual reimbursement prices," thus undercutting the "widespread assumption . . . that states with the same estimated acquisition cost formula pay similar prices." (*Id.*) To put it bluntly, OIG has *explicitly rejected* the very assumptions upon which Duggan relies to establish comparability between states.[22] Duggan admits that he ignored these critical factors entirely. (*Id.* ¶ 110.)[23]

It is not surprising, then, that Duggan's extrapolated "difference" calculation for the 39 no-data states leads to bizarre results. In some instances – such as when a state had an aggressive MAC – the "but-for" scenario created by Duggan suggests (without basis) that the states should have paid absurdly low amounts for drugs. For example, for the first quarter of 1997, Maryland imposed a MAC of $9.63 for NDC 00074653301 (Vancomycin 1 gm vial). (*Id.*

[22] Duggan also claims that he checked for "selection bias" by comparing the amount of Medicaid reimbursement "per claim" between his sample set and the extrapolated states. (*Id.* ¶ 112.) This comparison does not bolster Duggan's analysis for several reasons. First, the comparison covered only the years 1999 to 2001. Second, this analysis was done *before* he dropped Ohio from the sample set (a state he recognized as having lower per-claim reimbursements because of MACs). (*Id.*) Duggan has not produced a subsequent version of this analysis. Third, when asked why he did not at least exclude those NDCs where the per-claim reimbursement was *lower* in the extrapolated states, Duggan himself acknowledged the many variables that can affect his computation:

> [T]here are a number of reasons why it [reimbursement being lower per claim in extrapolated states] could be true. One would be the importance of the dispensing fee may differ between two states for two pairs of drugs. So for example you may have a drug, two states, one with a dispensing fee of 5, the other with a dispensing fee of 3, and, you know, there could be something else about the formula that would differ. There are just many factors. It could be something about the dispensing fee, something about the ingredient cost reimbursement, the number of units, the price that's being used and so forth. So there are a number of factors that could produce that.

(*Id.* ¶ 113.) Finally, as discussed in the next section, the significant variability in the dispensing fees paid for the type of infusion drugs at issue here renders Duggan's per-claim reimbursement analysis meaningless.

[23] Notably, Duggan's 10-state sample does not include any states that defined U&C to require providers to include prices accepted from third-party payers. (*Id.* ¶ 111.)

¶ 107.)[24] Duggan ignored this MAC, as he does all MACs, and simply applied a composite "difference ratio" derived from his 10-state sample to the total expenditures made by Maryland to arrive at a dollar value "difference." For this NDC-quarter (00074653301, Q1 1997), Duggan applies a difference ratio of 80.9104%. (*Id.*) In other words, Duggan reduces the payment on claims for this NDC-quarter by over 80%. Applying this difference ratio to Maryland's MAC-based payments for this product ($9.63) would lead to a per-unit payment of just $1.84 – well below even Duggan's estimate of what providers actually paid ($5.85) for this product. (*Id.*)[25] Duggan and the Plaintiffs thus seem to suggest that, if payment levels were properly set, providers in Maryland should have taken a 69% *loss* on each prescription of these products to a Medicaid patient.

Another example relates to Kansas, which in 1995 began paying providers at AWP minus 50% for "IV fluids" (like three of the four Subject Drugs: sodium chloride, dextrose, and sterile water). (*Id.* ¶ 137.) Kansas documents provide the following rationale for this change:

> Discounts from the reference pharmaceutical pricing schedule known as Average Wholesale Price (AWP) vary by product class. Generally, intravenous vehicles and irrigation solutions are available at much greater discounts than are other pharmaceuticals.

(*Id.*) Dr. Duggan ignored this information completely and applied his rigid extrapolation approach to Kansas, leading to absurd results throughout the time period. For instance, during the second quarter of 1997, the First Databank AWP for NDC 00074798436 (sodium chloride) was $10.76. (*Id.* ¶ 138.) Thus, a Kansas payment for one unit of this product would consist of a $5.38 ingredient cost payment ($10.76 minus 50%) and a dispensing fee of approximately $4.82, for a total payment of $10.20. Applying Duggan's "difference ratio" for this NDC-quarter

[24] Maryland established MACs for all of the products at issue here for much of the damage period. (*Id.* ¶ 105.) Not surprisingly, Duggan chose not to include Maryland in the 10-state "sample."

[25] The calculation is $9.63 minus Duggan's payment reduction of $7.79 ($9.63 times .809104) = $1.84.

(82.9193%) to the $10.20 payment would yield a "but-for" payment of just $1.74 ($10.20 - ($10.20 x .829193)) – $3.08 less than even the average *dispensing fee* and nothing at all for ingredient cost, resulting in the provider losing money for every unit dispensed to care for a Medicaid patient.

A final example – the last of what could be many – concerns Utah. When Utah implemented the so-called "DOJ AWPs" as the payment level for drug products, it recognized a need to significantly increase dispensing fees in the infusion context. (*Id.* ¶ 139) (April 2001 Utah document: "Home infusion pharmacy services have low volume and high expenditures. The DOJ's price list places the 'true AWP' close to actual acquisition costs, thus eliminating the 'spread' or profit that pharmacies have enjoyed for years."). Because the aggregate CMS payment data that Duggan used to calculate his dollar value "difference" for Utah and the other no-data states *includes dispensing fees* and not just drug payments,[26] his "differences" are not only falsely high, but they disregard Utah's expressed payment policies. For instance, the allegedly false claim with Steck_ID number 11148089[27] is a Utah claim adjudicated on September 17, 2001 for three units of NDC 00074653301 (Abbott's 1 gram of the Subject Drug vancomycin). (*Id.* ¶ 140.) Utah paid $50.04 on this claim – $22.90 for the increased dispensing fee that Utah established for infusion drugs and $27.14 for the three units of vancomycin. (*Id.*) Applying Duggan's "difference ratio" for this NDC-quarter (57.7262%) yields a new, "but-for" total payment of $21.15 ($50.04 - ($50.04 x .577262)). Once again, Duggan's approach creates a but-for scenario suggesting that the state should have paid providers *nothing* for the drugs

[26] As discussed above, Duggan calculated a dollar-value "difference" for the 39 no-data states by multiplying the aggregate expenditures for those states by the "difference ratio" that he derived from his 10-state sample.

[27] Plaintiffs have engaged Steck Consulting to assist Dr. Duggan in his evaluation of claims data. Steck provided "Steck _ ID" numbers for claims at issue.

dispensed and less in total than what the state had specifically established as the *dispensing fee* for this sort of infusion product. So, whereas Utah expressly intended to pay both a drug cost and an enhanced dispensing fee, Duggan's analysis wipes out those facts, calculates a "difference" figure that has no relationship to reality, and then assigns that baseless number as damages against Abbott. These among many absurd results pervade Duggan's extrapolation, yet he did nothing to evaluate, eliminate, or control for them.

The problem is hardly limited to just these states. As discussed in Abbott's memorandum in support of its motion for summary judgment, there are important issues unique to the type of drugs at issue here that Duggan has ignored entirely. Like Utah, many of the 39 no-data states developed specialized methods to provide additional payments to home healthcare providers to account for the heightened costs of that care, including methods that deliberately paid a margin on ingredient cost for intravenous products like the Subject Drugs at issue here to cover the higher costs of dispensing them. (*Id.* ¶¶ 21-27, 30, 38, 141.) For example, evidence indicates that Oregon paid for intravenous prescriptions at 80% of usual and customary charges; Montana paid the lower of U&C or 2.5 times the cost of ingredients plus a dispensing fee; and Massachusetts paid a "mark up" on the drug depending on the cost of the drug (lower priced products like the Subject Drugs received a higher mark up). (*Id.* ¶ 21.) These payment methodologies may have nothing to do with Abbott's reported prices. Duggan ignored these issues, yet still purports to extrapolate a "difference" to each of these states based on his upwardly-biased, 10-state partial sample.

The wide variation in how states determined dispensing fees for the Subject Drugs exposes yet another significant flaw in Duggan's analysis. As noted, the aggregate payment data Duggan used to compute his extrapolated dollar-value "difference" *includes dispensing fees*. (*Id.*

¶ 135.) This is a critical flaw in his methodology that, again, has the effect of artificially increasing the alleged damages. Recall that Duggan calculates his extrapolated dollar-value "difference" for the 39 no-data states by calculating a "difference ratio" (essentially an overpayment percentage) from his 10 partial-data states and then multiplying that ratio by the total aggregate expenditures in the 39 no-data states. If those aggregate expenditures included dispensing fees (and they did), then Duggan's dollar value "difference" includes not just drug payments, but also dispensing fees (which cannot legitimately be included in Plaintiffs' damages). Duggan ignored this issue, too.

As noted by Abbott's expert, Steve Young, the Myers & Stauffer reimbursement summaries and other evidence indicate this is a significant problem in Duggan's extrapolation. As previously noted, many states – including at least 15 of the 39 no-data states – developed enhanced dispensing fees for home infusion and compounded drugs. (*Id.* ¶ 141.) For example:

- Minnesota paid an additional dispensing fee of $8.00 per bag for infusion drugs requiring compounding. (*Id.*)
- Maryland paid a dispensing fee of $7.25 to $7.70 *per day* for home iv therapy prescriptions (versus the ordinary $4.21 per prescription fee). (*Id.*)
- Nevada paid a dispensing fee of $16.80 for the first dose of an intravenous medication, and $5.60 for the second dose given concurrently. (*Id.*)
- When Utah implemented the DOJ AWPs, it created much higher dispensing-fee levels (up to $33.90) for the NDCs included within the DOJ AWPs. (*Id.*)

By contrast, only two of the states in Duggan's 10-state sample (Michigan and Wisconsin) had enhanced fees, and Duggan only reviewed five quarters of Michigan data (out of the 44 quarters at issue). (*Id.*) As a result, Duggan's "difference" calculation is both unreliable and overstated, and it purports to charge Abbott with damages for the dispensing fees that various states chose to pay.

At bottom, states are not homogenous when it comes to Medicaid payments. Because

Duggan's sample does not include any claims from the 39 extrapolated states, the sample is by no means "appropriately representative of the larger entity or population being measured." *Allgood*, 2006 WL 2669337, at *11. As important, Duggan cannot even test whether his sample is representative, because the data necessary to do so either no longer exists or Duggan chose not to review it. This, too, renders Duggan's extrapolation inadmissible. *See Collyer*, 94 F.Supp. at 498-99 (refusing to allow extrapolation of results from one set of contracts to another set where plaintiff could not establish that the former was appropriately representative of the latter); *Albert*, 234 F. Supp. 2d at 106 n.7 ("there is no basis whatsoever for an extrapolation from the nursing home market to the hospital market"); *Whipple*, 2002 WL 864246, at *12.

2. Within State Extrapolation.

In addition to his extrapolation across states, Duggan also resorted to extrapolation within the 10 states where he had some data, in order to cover gaps. This intra-state extrapolation, too, is not an adequate substitute for review of the missing claims data. Among other things, Duggan did not evaluate whether factors that impact how the particular states paid for the Subject Drugs, such as the existence of MACs and the frequency with which drugs were paid for on the basis of U&C, changed over time. (*Id.* ¶ 122.)

Duggan's evaluation of the claims data that he does have for these 10 states underscores this problem. Where he had detailed data, Duggan determined the percentage of claims reimbursed on the basis of U&C. (*Id.* ¶ 130.) Duggan's analysis shows considerable variability within a given state over time in the percentage of claims reimbursed at U&C, and a general decline across the states in the percentage of claims reimbursed on that basis. (*Id.*). For example, in Illinois, which produced a relatively full set of data, Duggan found that the percentage of U&C-based payments declined from 76.90% in 1992 to 12.76% in 2001. (*Id.*) Despite this wide variability in Illinois, which produced substantial data across the entire time

period, Duggan nevertheless assumes for a large state like Michigan that the data produced for the last five quarters of the damages period (all he was given) is representative of all prior quarters where no data was produced. In light of the contrary experience in Illinois, this is almost certainly a false assumption. These lapses in Duggan's analysis are critical, because U&C-based payments are not related to Abbott's reported prices and should not be assigned as damages. Duggan's failure to account for this sort of variability in payment bases renders any extrapolation to earlier time periods for which he lacks data within a state unreliable and overstated, and the Court can have no confidence in his results.[28]

C. Medicare.

1. Across Carrier Extrapolation.

As with Medicaid, the sample set used in Duggan's Medicare extrapolation is far from random. Rather, Duggan simply uses some pricing arrays from some Carriers that were available. (*Id.* ¶¶ 116-117.) This is itself a sufficient reason to deny recovery for claims paid by the extrapolated Carriers.

Even more significant is the tremendous variability in the pricing arrays at issue. Duggan admits that "[t]he NDCs that are included in an array vary across Carriers and can vary within the same Carrier over time." (*Id.* ¶ 145.) That is an understatement. The J-Codes at issue here – particularly the saline and dextrose J-Codes that feature prominently in Duggan's extrapolated "difference" – involved products manufactured by numerous manufacturers *and* available in multiple dosage sizes and package offerings. (*Id.*) As a study done for CMS in 2002 demonstrates, these factors increase significantly the possible combinations of particular NDCs a

[28] Because U&C served as the basis for payment only when it was lower than EAC, claims reimbursed at charges would have a lower "difference" than claims reimbursed on the basis of EAC. Extrapolating from a period with a higher percentage of EAC-based reimbursements to a period with a lower percentage of EAC-based reimbursements would thus serve to overstate the "difference" in the extrapolated period.

Carrier might include in an array. (*Id.* ¶ 146. "Confusion between the Carriers increased as multiple source drugs appeared under the HCPCS Code (Table 5). Higher rates of disagreement for reimbursable amounts also appeared as larger numbers of RedBook prices became available.").) In sum, there is no way to determine what information any one Carrier might have included in the arrays used to set these J-Code payment levels without seeing them.

And the importance of this unknowable fact cannot be underestimated, for a change in the makeup of the arrays among Carriers can result in dramatic differences in the allowable payment amount (and thus in Duggan's "differences"). To illustrate the point, consider the "differences" Duggan computes in the following two arrays for the same J-Code quarter (J7050, Q3 2000), produced by Cigna and Wisconsin Physician Services ("WPS"):

2000 Pricing ***J7050***

CODE	DESCRIPTION	UNIT DOSAGE	PRICING DRUG NAME / MANUFACTURE	INFO DATE	LISTED DOSAGE PER REDBOOK	ML	AWP RED BOOK	COST UNIT/ DOSAGE
J7050	Infusion, Normal Saline Solution	250 cc	Sodium Chloride (Abbott Hosp)	2000 ann	Lifecare plastic .9% 250 ml 24's	24	$ 278.73	$ 11.61
			B. Braun McGaw	2000 ann	(excel) .9% 250 ml	1	$ 10.69	$ 10.69
			Baxter	2000 ann	Single-pack 250 ml 36's	36	$ 327.89	$ 9.11

J7050	Sodium Chloride	250 cc	Abbott	12's	148.20	12.35	
	(Normal) - (0.9%)	250cc	Abbott	24's	406.70	16.95	
	~~00074-7983-01~~ 00074-1583-02	250cc	Abbott	24's	278.73	11.61	X
Nic	00074-7101-02	250cc	Braun McGaw	0.9% 250ml	10.69	10.69	X
1-8-2008	00074-7983-02	250 cc	Baxter	12's	116.06	9.67	
		250cc	Baxter	36's	327.89	9.11	

(*Id.* ¶¶ 150-151.) Cigna included 3 NDCs, one NDC each from Abbott, McGaw, and Baxter, while WPS included 6 NDCs, three from Abbott, one from McGaw, and two from Baxter.

Duggan's approach was to insert his "but for" AWP into the arrays and determine any change in the median AWP, and thus the payment level. If the median AWP/payment level went down as a result of this substitution, Duggan then assigned the difference between what the Carrier actually paid and this new payment level as a dollar value "difference," which Plaintiffs now claim as damages against Abbott. But this same exercise for the two Carriers above yields

wildly different results. In the Cigna array, Duggan's approach changes the median from $10.69 to $9.11 – a 14.8% decrease. (*Id.* ¶ 150.) In the WPS array, however, Duggan's approach changes the median from $11.15 to $5.82 – a 47.9% decrease. (*Id.* ¶ 151.) Thus, using the same exact change in AWP (from the compendia version to Duggan's "but for" version), he obtains dramatically different changes in the median between these two Carriers, which leads to vastly divergent "differences" (i.e., damages amounts). Critically, this phenomenon is entirely the result of the particular mix of NDCs that these two Carriers happened to use in their arrays. This example underscores the importance of knowing and accounting for the precise arrays utilized by the Carriers across the time period at issue – something Duggan did not, and cannot, do.

At bottom, Duggan's effort to extrapolate a "difference" from one set of Carriers (which did produce arrays) to another set of Carriers (which did not) is hopelessly speculative. It is not based on a random sample of claims processed by all Carriers, but rather a "convenience sample garnered by a unit whose purpose is to investigate fraud." *Skoknek*, 933 F. Supp. at 1115-18. Thus, testimony regarding extrapolation between Carriers must be excluded.

2. Within Carrier Extrapolation.

Duggan's attempt to extrapolate findings to different time periods within the same Carrier suffers similar fatal flaws. This extrapolation assumes that the magnitude of "difference" (resulting from replacing compendia AWPs for the Subject Drugs with Duggan's "but for" AWPs) would be similar throughout the period 1991-2001 for a given Carrier. Because Duggan's "difference" depends primarily on the mix of NDCs contained in the arrays, however, his extrapolation to different time periods within the same Carrier depends upon a consistency in the NDC mix used by that Carrier over time. Duggan admits, however, that "[t]he NDCs that are included in an array vary across Carriers and *can vary within the same Carrier over time*." (*Id.* ¶ 145.) (emphasis added).

The pricing arrays that were produced bear out Duggan's observation. For example, the arrays for J7050 produced by Cigna each used the same manufacturers, but a different NDC mix.

	1997	1999 Q2	2000 Q2	2000 Q3	2001 Q3
Abbott	74-7101-02: **$13.93**				74-7101-02: **$16.95**
	74-1583-02: **$10.15**	74-1583-02: **$11.75**			74-1583-02: **$12.35**
	74-7983-02: **$9.56**		74-7983-02: **$11.61**	74-7983-02: **$11.61**	74-7983-02: $**11.61**
	74-6138-02: **$12.14**				
					74-7985-02: **$12:35**
					74-7132-02: **$16.95**
Baxter	NDC not identified: **$4.96**				
	NDC not identified: **$9.67**				00338-0049-02: **$9.67**
	NDC not identified: **$11.56**				
	NDC not identified: **$9.11**	NDC not identified: **$9.10**	00338-0049-02: **$9.11**	NDC not identified: **$9.11**	00338-0049-02: **$9.11**
McGaw	NDC not identified: **$10.26**				
		NDC not identified: **$12.30**			
			00264-7800-02: **$10.69**	NDC not identified **$10.69**	00264-7800-02: **$10.69**

(*Id.* ¶ 155.)

Importantly, about half of Duggan's "difference" attributable to within-Carrier extrapolation relates to Florida Blue Shield. (*Id.* ¶ 153.) For four of the five J-Codes at issue, Florida Blue Shield produced arrays for just two quarters (Q1 and Q2 1997). (*Id.* ¶ 156.) There is no way to evaluate whether this or any other Carrier consistently included the same mix of NDCs in its arrays over time. The Florida Blue Shield 30(b)(6) witness testified that she included only one NDC per manufacturer when she started preparing arrays in 1997, but she did not know whether this practice was followed throughout the 1991-2001 time period. (*Id.*)

In sum, because Duggan does not know what mix of NDCs were included in Carrier arrays that were not provided to him, and because he has no valid basis on which to compare the

NDCs used in the missing arrays to his sample, Duggan cannot predict with any reasonable certainly the impact, if any, of using revised AWPs for any Abbott NDC. This aspect of Duggan's opinions should be excluded, as well.

CONCLUSION

For the foregoing reasons, the Court should enter an order excluding Duggan from offering testimony regarding any aspect of his "difference" computation that relied upon extrapolation.

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Respectfully submitted,

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Counsel for Defendant Abbott Laboratories Inc.

CERTIFICATE OF SERVICE

I, David S. Torborg, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES, INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION *IN LIMINE* TO EXCLUDE CERTAIN OPINIONS PROFFERED BY PLAINTIFFS' EXPERT MARK G. DUGGAN, PH.D. to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 26th day of June, 2009.

/s/ David S. Torborg
David S. Torborg